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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,622	03/01/2004	Ragina Naidu	740082.408C1	8831

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EXAMINER

CHANG, CELIA C

ART UNIT PAPER NUMBER

1625

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/790,622

Applicant(s)

NAIDU, RAGINA

Examiner

Celia Chang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 29 March 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                                   |                                                                                         |
|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                              | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

### DETAILED ACTION

1. Amendment and response filed by applicants dated Mar. 29, 2005 have been entered and considered carefully.

Claims 1-7 have been canceled. Claims 8-13 and newly added claims 14-25 are pending.

2. Applicant's arguments with respect to claims 8-25 have been considered but are moot in view of the new ground(s) of rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kingston et al. US 5,470,866 (recited in previous PTO-892) in view of Kingston et al. '866, Gennari et al. I (pur & appl Chem), or Gennari II (J. Braz. Chem. soc.) or Chen et al. CA 123:112445.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Kingston et al. '866 disclosed analogous process for making the same product of the claims, see whole article especially fig. 1-5 general scheme.

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

The difference between the instant claims and the analogous process of Kingston et al. '866 is that instead of the steps and hydroxyl-protected intermediates as disclosed by Kingston,

Art Unit: 1625

the instant claims are drawn to alternative o-protected intermediates. Kingston '866 disclosed the Boc-protected Baccatin III(see col. 23 lines 50-65) and other alternative protected species by conventional method of hydroxyl protection. Chen et al. disclosed that the Boc- or benzyol protection of the Baccatin III are alternative choices for the field. Gennari I or II in elucidation of how the key intermediate Baccatin III was formed during synthetic processes, the aziridinyll intermediate as well as the epoxy-intermediates were delineated (see I, p. 510 fig. 6 and 7, II p. 323 fig. 6 and 7)

*Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)*

One having ordinary skill in the art in possession of the above references would be in possession of the instant claims since the optional choices of operable O-protecting was exemplified including the Boc-key product of the instant process (see '866 col. 23 last compound vs instant claim 13), the mix and match of the different step such as ring closure first, then condensation or condensation then ring closure etc. are prima facie changing sequence in chemical derivatization well recognized being prima facie of the chemical synthetic field. Especially, although, the aziridinyll or epoxy intermediates were not explicitly exemplified in the prior art, the elucidation of mechanism by Gennari clearly pointed to the formation and stability of such intermediates. The mere inclusion of intermediates which are conventionally known to be innately formed by the process is prima facie obvious. In absence of unexpected results, there is nothing unobvious in isolating or not isolating an intermediate for a conventional process

3. Claims 8-25 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-58 of copending SN 10/695,416 or claims 1-74 of copending SN 10/881,711 in view of Gennari et al. I(pur & appl Chem), or Gennari II(J. Braz. Chem. soc.) or Chen et al. CA 123:112445.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Generically, the instant processes of claims 8-25 are fully encompassed by the copending claims (see claims 1-58 of SN 10/695,416, or claims 1-74 of SN 10/881,711) wherein the scope of the process for the free hydroxyl moieties are broadly claimed being hydroxyl protecting groups.

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

The difference between the instant claims and the more specific dependent claims in the explicit O-protecting groups i.e. acyl vs *t*-BuO, etc, are conventional *analogous* hydroxyl-protected intermediates as disclosed by Kingston, Gennari I or II, or Chen. Kingston '866 disclosed the Boc-protected Baccatin III(see col. 23 lines 50-65) and other alternative protected species by conventional method of hydroxyl protection. Chen et al. disclosed that the Boc- or benzyol protection of the Baccatin III are alternative choices for the field. Gennari I or II in elucidation of how the key intermediate Baccatin III was formed during synthetic processes, the aziridinyll intermediate as well as the epoxy-intermediates were delineated (see I, p. 510 fig. 6 and 7, II p. 323 fig. 6 and 7)

*Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)*

Art Unit: 1625

One having ordinary skill in the art in possession of the above references would be in possession of the instant claims since the optional choices of operable 0-protecting was exemplified including the Boc-key product of the instant process (see '866 col. 23 last compound vs instant claim 13), the mix and match of the different step such as ring closure first, then condensation or condensation then ring closure etc. are prima facie changing sequence in chemical derivatization well recognized being prima facie of the chemical synthetic field. Especially, although, the aziridinyl or epoxy intermediates were not explicitly exemplified in the prior art, the elucidation of mechanism by Gennari clearly pointed to the formation and stability of such intermediates. The mere inclusion of intermediates which are conventionally known to be innately formed by the process is prima facie obvious. In absence of unexpected results, there is nothing unobvious in isolating or not isolating an intermediate for a conventional process.

This is a provisional obviousness-type double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

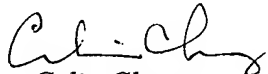
4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1625

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*OACS/Chang*  
*Aug. 30, 2005*

  
*Celia Chang*  
*Primary Examiner*  
Art Unit 1625